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07-CV-00248-CMP

UNITED STATES DISTRICT COURT, WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA ex rel. MARSHALL S. HORWITZ, M.D.,

Plaintiff,

v.

AMGEN INC.; and DAVID C. DALE,

Defendants.

No. C 07-0248 JCC

COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. § 3729 *et seq.*]; CALIFORNIA FALSE CLAIMS ACT [Cal. Govt. Code § 12650 *et seq.*]; DELAWARE FALSE CLAIMS AND FALSE REPORTING ACT [6 Del. C. § 1201]; FLORIDA FALSE CLAIMS ACT [Fla. Stat. Ann. § 68.081 *et seq.*]; HAWAII FALSE CLAIMS ACT [Haw. Rev. Stat. § 661-21 *et seq.*]; ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT [740 Ill. Comp. Stat. § 175 *et seq.*]; MASSACHUSETTS FALSE CLAIMS LAW [Mass Gen Laws ch.12 § 5 *et seq.*]; NEVADA FALSE CLAIMS ACT [Nev. Rev. Stat. Ann. § 357.010 *et seq.*]; TENNESSEE MEDICAID FALSE CLAIMS ACT [Tenn. Code Ann. § 71-5-181 *et seq.*]; TEXAS MEDICAID FRAUD PREVENTION LAW [Tex. Hum. Res. Code Ann. § 36.001 *et seq.*]; VIRGINIA FRAUD AGAINST TAXPAYERS ACT [Va. Code Ann § 8.01-216.1 *et seq.*]; and DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT [D.C. Code Ann. § 1-1188.13 *et seq.*]

FILED IN CAMERA AND UNDER SEAL
(pursuant to 31 U.S.C. § 3730(b)(2))

ORIGINAL

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Plaintiff and Relator Marshall S. Horwitz, through his attorneys Hagens Berman Sobol Shapiro LLP, and on behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Hawaii, the State of Illinois, the State of Massachusetts, the State of Nevada, the State of Tennessee, the State of Texas, the State of Virginia and the District of Columbia (collectively "the States and the District of Columbia"), and for his Complaint against defendants Amgen Inc. and David C. Dale, alleges based upon personal knowledge and relevant documents, as follows.

I. INTRODUCTION

1. This is an action (1) to recover damages and civil penalties on behalf of the United States of America, the States and the District of Columbia arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by defendant Amgen Inc. ("Amgen") and/or its agents and employees, and David C. Dale ("Dale") in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq.*, as amended ("the FCA" or "the Act").

2. As set forth below, defendants' acts also constitute violations of the California False Claims Act, Cal. Govt. Code § 12650 *et seq.*; the Delaware False Claims and False Reporting Act, 6 Del. C. § 1201 *et seq.*; the Florida False Claims Act, Fla. Stat. Ann. § 68.08 *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Compo Stat. § 175/1-8; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 § 5 *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§ 357.010 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.*; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq.*; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§ 1-1188.13 *et seq.*

3. Amgen and Dale have falsely promoted the use of Aranesp through the publication of articles promoting uses of Aranesp in a manner that is not approved by the FDA

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and which in fact may increase the risk to patients of mortality and cardiovascular and other side effects. These articles were "ghost written" by Amgen, meaning Amgen and its agents wrote much of the articles and that each article evidences a common authorship. Defendant Dale was listed as the author in one of these articles and did not disclose Amgen's involvement in publication of the article. Those in the medical community would believe this article was written by a prominent and independent physician, and as such would consider the views of Dr. Dale in deciding a course of treatment. Doctors relying on such articles would be unaware that Dale and the other purported authors were not the true authors – Amgen and/or its agents were. But Amgen was not permitted by federal law to promote an off-label use. The Dale article and similar ghost written articles promoted "front loading" of Aranesp. "Front loading" is not approved by the FDA. By arranging for Amgen's consultants to write the articles for Dr. Dale and the others, Amgen circumvented the law prohibiting a manufacturer from promoting off-label use.

4. The same ghost writing practice occurred with respect to Amgen's drug Neulasta. There Dr. Dale and other authors, in papers that were largely written by Amgen, promoted Neulasta as superior to Amgen's older drug Neupogen. Neulasta is Amgen's second largest revenue producing drug. Amgen did not receive FDA approval for promotion of Neulasta as superior to Neupogen.

5. As a direct result of defendants' improper practices, federal and state health programs including, but not limited to, Medicare, Medicaid, Medi-Cal, CHAMPUS/TRICARE, CHAMPV A, the Veterans Administration and the Federal Employee Health Benefits Program have been caused to pay false or fraudulent claims for reimbursement for prescriptions of Aranesp and Neulasta in populations other than those indicated for treatment – prescriptions that would not have been paid but for the defendant's illegal business practices.

6. The False Claims Act was originally enacted during the Civil War and was substantially amended in 1986. Congress amended the Act to enhance the Government's ability

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to recover losses sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive, and that the Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments create incentives for individuals with knowledge of fraud against the Government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

7. The Act provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. Liability attaches when a defendant knowingly seeks payment, or causes others to seek payment, from the Government that is unwarranted.

8. The Act allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

9. Since the passage of the federal False Claims Act, a number of states have passed similar statutes that authorize private persons to file suits to recover damages for false claims presented for payment from state funds. Based on these federal and state provisions, *qui tam* plaintiff seeks through this action to recover damages and civil penalties arising from Amgen's making or causing to be made false or fraudulent records, statements and/or claims in connection with its marketing of its prescription drugs. Defendants knew that its false and fraudulent marketing practices would cause the submission of hundreds of thousands of claims to federal and state health insurance programs for medically unnecessary and potentially harmful prescriptions for Aranesp and Neulasta.

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II. PARTIES

10. Plaintiff/relator Dr. Marshall S. Horwitz, M.D. is a resident of Washington. Dr. Horwitz at all relevant times was employed by the University of Washington.

11. Defendant Amgen Inc. is a publicly traded company, incorporated in Delaware, with corporate headquarters and its principal place of business in Thousand Oaks, California. With revenues of $12.4 billion in 2005, Amgen is one of the largest pharmaceutical companies in the United States.

12. David C. Dale ("Dale") is a resident of Washington and an M.D. employed by the University of Washington.

III. JURISDICTION AND VENUE

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. In addition, 31 U.S.C. § 3732(b) specifically confers jurisdiction on this Court over the state law claims asserted in this Complaint. Under 31 U.S.C. § 3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

14. This Court has personal jurisdiction and venue over the defendants pursuant to 28 U.S.C. §§ 1391(b) and 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the defendants have minimum contacts with the United States. Moreover, the defendants can be found in, reside, transact, or have transacted business in this district.

15. Venue is proper in this District pursuant to 32 U.S.C. § 3732(a) because the defendants can be found in and transact or have transacted business in this District. At all times relevant to this Complaint, defendants regularly conducted substantial business within this District, and made significant sales within the District. Venue is proper in this District pursuant to Title VII, 42 U.S.C. § 2000e-5 (f)(3) because the unlawful practices complained of herein were committed within this District.

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IV. BACKGROUND

A. The FDA Regulatory Scheme

16. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final stage of a multi-year process of study and testing.

17. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use is called the "indication" for which the drug may be prescribed. The FDA will specify particular dosages determined to be safe and effective for each indication.

18. The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also reviewed by the FDA. 21 U.S.C. §§ 352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. § 355(d).

19. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), if a manufacturer wishes to market or promote an approved drug for additional uses – *i.e.*, uses not listed on the approved label – the manufacturer must resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. § 360aaa(b), (c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label."

20. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or

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frequency than specified in the label, or treating a different patient population (*e.g.*, treating a child when the drug is approved to treat adults).

21. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different than those approved by the FDA.

22. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. Specifically, under the Food and Drug laws, a manufacturer illegally "'misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352.

23. An off-label use of a drug can cease to be off-label only if the manufacturer submits a supplemental application and demonstrates to the satisfaction of the FDA that the product is safe and effective for the proposed new use. 21 U.S.C. § 360aaa(b), (c).

24. In addition to prohibiting manufacturers from directly marketing and promoting a product's unapproved use, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. For example, FDA regulates two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products; and (2) manufacturer support for Continuing Medical Education ("CME") programs that focus on off-label uses.

25. With regard to the first practice – disseminating written information – the FDAMA only permits a manufacturer to disseminate information regarding off-label usage in response to an "unsolicited request from a health care practitioner." 21 U.S.C. § 360aaa-6. In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA

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seeking approval of the drug for the off-label use; has provided the materials to the FDA prior to dissemination; and the materials themselves must be in an unabridged form and must not be false or misleading. 21 U.S.C. §§ 360aaa(b), (c); 360aaa-l.

26. In sum, the off-label regulatory scheme protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body – the FDA.

B. The Anti-Kickback Statute

27. The federal health care Anti-Kickback statute, 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

28. The Anti-Kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). Under this statute, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend drugs that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company that has as one of its purposes inducement of a physician to write additional prescriptions for the company's pharmaceutical products.

29. Violation of the Anti-Kickback statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§ 1320a-7(b)(7), 1320a-7a(a)(7).

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30. Concern about improper drug marketing practices prompted the Inspector General of the Department of Health and Human Services ("HHS") to issue a Special Fraud Alert in 1994 identifying prescription drug marketing practices that violate the Anti-Kickback law. Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 19, 1994).

31. In May 2003, the Inspector General of HHS released a further Guidance identifying in greater detail several marketing practices of drug manufacturers that constitute "kickbacks and other illegal remuneration" affecting federal health care programs. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) (the "2003 Guidance").

32. The 2003 Guidance specifically cautions manufacturers that sponsored educational programs for physicians – in effect, providing free CME credits to those physicians – could constitute illegal kickbacks, as follows: "CME programs with no industry sponsorship, financing, or affiliation should not raise anti-kickback concerns, although tuition payments by manufacturers (or their representatives) for persons in a position to influence referrals (*e.g.*, physicians or medical students) may raise concerns." *Id.* at 23742 n. 11.

33. Compliance with the Anti-Kickback law is a precondition to participation as a health care provider under the Medicare, Medicaid, CHAMPUS/TRICARE, CHAMPV A, Federal Employee Health Benefit Program, and other federal health care programs. With regard to Medicaid, for example, each physician and pharmacist that participates in the program must sign a provider agreement with his or her state. Although there are variations in the agreements among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all Medicaid requirements, which include the anti-kickback provisions of the law. In New York and a number of other states, the Medicaid claim form itself contains a certification by the provider that the provider has complied with all aspects of the Medicaid program, including compliance with Federal laws.

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34. Thus, either pursuant to provider agreements, claims forms, or in another appropriate manner, pharmacists and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback law.

35. Any party convicted under the Anti-Kickback statute must be excluded (*i.e.*, not allowed to bill for services rendered) from federal health care programs for a term of at least five years. 42 U.S.C. § 1320a-7(a)(1). Even without a conviction, if the Secretary of HHS finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant State agency(ies) to exclude that provider from the State health program), and may consider imposing administrative sanctions of $50,000 per kickback violation. 42 U.S.C. § 1320a-7(b).

36. The enactment of these various provisions and amendments demonstrates Congress's commitment to the fundamental principle that federal health care programs will not tolerate the payment of kickbacks. Thus, compliance with the Anti-Kickback statute is a prerequisite to a provider's right to receive or retain reimbursement payments from Medicaid and other federal health care programs. Reimbursement is also prohibited by the general legal principle that providers who are corrupt or unethical or violate the integrity of a government program involving government funds are not entitled to payment from the public fund for the resulting claims.

C. Prescription Drug Payment Under Federal Health Care Programs

1. The Medicaid Program

37. Whether an FDA approved drug is listed for a particular indication (*i.e.*, use) determines whether a prescription for that use may be reimbursed under Medicaid and other federal health care programs.

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38. Medicaid is a public assistance program providing for payment of medical expenses for low-income patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

39. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. § 1396b(1)(10), 1396r-8(k)(2), (3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." *Id.* § 1396r-8(k)(3).

40. A medically accepted indication, in turn, is a use which is listed in the labeling approved by the FDA, or which is included in one of the drug compendia identified in the Medicaid statute. *Id.* § 1396r-8(k)(6). During the time period relevant to this Complaint, the off-label uses of Aranesp and Neulasta promoted by Amgen were not eligible for reimbursement from Medicaid because the drug's off-label uses were neither listed in the labeling approved by the FDA nor included in any of the drug compendia specified by the Medicaid statute.

2. Medicare Program

41. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added prescription drug benefits to the Medicare program.

42. The Medicare Prescription Drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 USC § 1396r-8(k) (as described in paragraphs 39 and 40 above).

43. The first stage of the Medicare program, from May 2004 through December 2005, permits Medicare beneficiaries to enroll in a Medicare-approved drug discount card program.

44. In addition, low income beneficiaries, defined as those whose incomes are not more than 135% of the poverty line (those with incomes of no more than $12,569 for a single

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person or $16,862 for a married couple in 2004) qualify for a $600 credit (funded by Medicare) on their drug discount card for 2004 and again for 2005.

Separate from Medicare programs qualifying recipients on the basis of age or income is the Medicare End Stage Renal Disease Program, a national health insurance program for people with end stage renal disease. Administration of recombinant forms of human erythropoietin is a mainstay of the treatment of anemia associated with chronic renal failure. In 2005, the End Stage Renal Disease Program covered about 390,000 beneficiaries and spent $2.9 billion for medications. Recombinant forms of erythropoietin accounted for more than $2 billion of this spending and erythropoietin was the highest-expenditure drug in all of Medicare Part B

45. Starting in January 2006, Part D of the Medicare Program provided subsidized drug coverage for all beneficiaries. Low income individuals will receive the greatest subsidies. Aranesp and Neulasta will be utilized by Part D beneficiaries.

46. During the time period relevant to this Complaint, the off-label uses of Aranesp and Neulasta promoted by Amgen were not eligible for reimbursement from Medicare because those off label uses were neither listed in the labeling approved by the FDA nor included in any of the drug compendia specified by statute. The federal government spent billions on reimbursement of each of these drugs.

3. Reimbursement under other federal health care programs

47. In addition to Medicaid and Medicare, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs, including but not limited to CHAMPUS/TRICARE, CHAMPV A and the Federal Employees Health Benefit Program.

48. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPV A, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disability. The Federal

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Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors. Coverage of off-label drug use under these programs is similar to coverage under the Medicaid program. *See, e.g.*, TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15,2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

49. During the time period relevant to this Complaint, the off-label uses of Aranesp and Neulasta promoted by Amgen were not eligible for reimbursement under any of the various federal health care programs.

4. Direct purchases by federal agencies

50. In addition to reimbursing drug purchases through Medicare, Medicaid, and other federal health care programs, the United States is a significant direct purchaser of prescription drugs through various federal programs. Defendant's illegal and misleading off-label promotion of Aranesp and Neulasta has resulted in increased purchases of these drugs by these programs, including, but not limited, to the following.

a. Programs administered by the Department of Veterans Affairs

51. The Department of Veteran Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are dispensed to beneficiaries. It also supports a mail service prescription program as part of the outpatient drug benefit. The system serves approximately four million veterans. The VA directly purchases prescription drugs, including Aranesp and Neulasta, that are dispensed through these facilities and programs.

b. Programs by the Department of Defense

52. The Department of Defense ("DOD") provides prescription drug coverage to approximately eight million active duty personnel, retirees, and their families through three points of service: military treatment facility outpatient pharmacies, TRICARE managed care contractor retail pharmacies, and the National Mail Order Pharmacy Program. DOD negotiates

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independent contracts to purchase the majority of the prescription drugs, including Aranesp and Neulasta, provided through these programs.

D. The FDA-Approved Indications for Aranesp, Neupogen and Neulasta

53. **Aranesp.** Introduced in 2001, Aranesp (darbepoetin alfa) is approved in the United States, most countries in Europe, Canada, Australia, and New Zealand for the treatment of anemia associated with chronic renal failure in patients both on dialysis and not on dialysis. In 2002, Aranesp was also approved in the United States and Europe for the treatment of chemotherapy-related anemia. Aranesp is a recombinant erythropoietic protein that stimulates production of oxygen-carrying red blood cells, with greater biological activity and a longer half-life than Epoetin alfa.

54. **Neupogen.** Neupoge (filgrastim), launched in 1991 in the U.S. and Europe, is a recombinant version of a human protein that selectively stimulates the production of infection-fighting white blood cells, called neutrophils. It is indicated to decrease the incidence of infection as manifested by febrile neutropenia in patients with non-myeloid malignancies receiving myelo-suppressive anti-cancer drugs.

55. **Neulasta**. Neulasta (pegfilgrastim) received approval in 2002 in the United States and Europe for reducing the incidence of infection from chemotherapy-induced neutropenia in cancer patients with non-myeloid malignancies. Neulasta, a longer-acting form of Filgrastim than Neupogen, has been shown to decrease the incidence of infection as a result of chemotherapy-induced neutropenia with a once-per-cycle injection.

56. Three erythropoietic drugs are currently approved for certain indications for the treatment of anemia in the United States: recombinant erythropoietin alfa (Epogen and Procrit) and darbepoetin alfa (Aranesp). Two drugs with selective granulocyte colony stimulating factor activity, filgrastim (Neupogen) and PEG-filgrastim (Neulasta), are currently approved in the United States for certain indications for the treatment of neutropenia. Although Epogen, Procrit, and Aranesp compete with one another, as do Neupogen and Neulasta, all five are manufactured

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by Amgen. Of this class of blood cell growth factors, Epogen, Procrit, and Neupogen are considered "first generation" drugs. Epogen and Procrit were first approved by the FDA in 1993. Neupogen was first approved in 1991. Each of these first generation drugs are each covered by multiple patents, which are expected to expire over a timeframe extending from 2006 to 2011. "Second generation" glycosylation variants of these drugs have been more recently introduced; Aranesp was approved by the FDA in 2001 and Neulasta in 2002. Aranesp and Neulasta have extended patent protection and will be competing with other manufacturers' "biogeneric" versions of recombinant erythropoietin alfa and filgrastim, respectively, once patents protecting Amgen's first generation of drugs have fully expired.

57. Total U.S. sales for Aranesp in 2005 were $2.1 billion and for Neulasta $1.9 billion. In the first nine months of 2006, U.S. sales of Aranesp were $2.03 billion and for Neulasta $1.63 billion.

58. Anemia, for which Aranesp is used, is a condition that occurs when the blood does not contain enough red blood cells.

59. Red blood cells carry oxygen from the lungs to the body's tissues. In a healthy person, the body sends signals to the bone marrow to create more red blood cells whenever the body needs more oxygen. A hormone called erythropoietin, produced in the kidney, is the signal that stimulates the bone marrow to produce red blood cells. When the body does not produce enough erythropoietin, fewer red blood cells are produced, and therefore less oxygen is delivered to the body.

60. Certain diseases – such as cancer and chronic kidney disease – are related to anemia. Cancer patients undergoing chemotherapy often suffer from anemia because chemotherapy attacks not only cancerous cells, but other cells in the body as well, including red blood cells. In kidney disease patients, kidney function is reduced. Erythropoetin, the body's signal that tells bone marrow to make more red blood cells, comes from the kidneys, so in these patients, fewer red blood cells are produced.

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61. Some common symptoms of anemia include: fatigue, weakness, rapid heartbeat, shortness of breath, dizziness or fainting, feeling cold, sadness or depression, and shortness of breath. Anemia can strain the heart as it overworks to deliver oxygen throughout the body. It also can make certain cancer therapies less effective and can interrupt chemotherapy treatment. If left untreated, anemia can result in the need for red blood cells transfusions.

62. In some cases, blood disorders are related to other diseases and conditions. Chronic diseases like kidney disease can affect the production of erythropoietin, an important glycoprotein that stimulates the production of red blood cells. An inadequate number of red blood cells reduces the amount of oxygen delivered throughout the body and can represent a serious complication to patients of chronic illness.

63. In cancer patients, chemotherapy can cause blood disorders. Chemotherapy – the use of drugs to treat cancer – works by seeking and attacking fast-growing cells. In addition to attacking cancerous cells, chemotherapy also kills normal cells, including a certain type of white blood cell called neutrophils, which help the body fight infection. About half of the 1.6 million chemotherapy patients in the United States are at risk for developing lower than normal white blood cell counts – a condition called neutropenia. This places them at potential risk for infection and can postpone chemotherapy treatments. Neutropania is the condition that Neulasta is prescribed for.

E. Ghostwriting

64. The integrity of the published record of scientific research depends not only on the validity of the science but also on honesty in authorship. Editors and readers need to be confident that authors have undertaken the work described and have ensured that the manuscript accurately reflects their work, irrespective of whether they took the lead in writing or sought assistance from a medical writer. The scientific record is distorted if the primary purpose of an article is to persuade readers in favor of a special interest, rather than to inform and educate, and this purpose is concealed.

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65. Ghost authorship exists when someone has made substantial contributions to writing a manuscript and this role is not mentioned in the manuscript itself. WAME[1] considers ghost authorship dishonest and unacceptable. Ghost authors generally work on behalf of companies, or agents acting for those companies, with a commercial interest in the topic, and this compounds the problem. For example, a writer employed by a commercial company may prepare an article, then invite an expert in the field to submit the work, perhaps with minor revisions, under his or her own name. The submitting author may be paid, directly or indirectly, for this service. In other circumstances, investigators may pay a professional writer to help them prepare for their article but not mention this assistance, gaining credit for writing they have not done. Although editors of publications often seek to avoid publication of ghostwritten articles, these articles are often very difficult to detect.

66. Submitting authors bear primary responsibility for naming all contributors to manuscripts and describing their contributions. Ghost authorship would be avoided if corresponding authors listed everyone else who participated in the work, including those who contributed only to the writing, along with their individual contributions and institutional affiliations, stated explicitly how the work was paid for, and fully disclosed any further potential competing interests.

67. However, responsibility for ghostwritten manuscripts goes beyond individual authors. Other parties, including companies – such as marketing, communications, and medical education companies who are paid to assist pharmaceutical and medical device companies in disseminating favorable messages about their products – may initiate the sequence of events for which the author is the final and most easily identified participant.

68. Various participants in the medical field have incentives to ghostwrite articles.

[1] The World Association of Medical Editors ("WAME") is a community of 1170 medical editors of 733 journals who work together to facilitate cooperation and communication among editors of medical journals throughout the world. Members work to improve editorial standards and promote professionalism in medical editing through education, self-criticism, and self-governance. Paragraphs 63-66 are derived from a WAME paper on ghost writing.

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69. Academicians often wish to have as many publications associated with their names as possible. This may help in obtaining additional grants, promotions and consulting contracts.

70. Pharmaceutical companies also have motives for promoting such articles. An article written about these drugs lend the appearance of impartiality. If these articles promote off-label use they allow the company to be behind the scenes promoting such use so as to avoid a violation of federal law.

F. Amgen Ghostwrites Articles Promoting Off-Label Use of Aranesp

71. To promote its drugs Aranesp and Neulasta, Amgen contracted with Thomson Gardiner-Caldwell Communications ("GCC"). GCC holds itself out as a firm that works with pharmaceutical companies, including providing "medical writers." According to GCC's website:

> **Publication planning**
>
> TCGC has earned an enviable reputation for creating and managing publication planning strategies to communicate key clinical data in a timely and appropriate way. TGCG uses its experienced publication and Medical and Scientific Services teams to design publication plans with maximum impact that are also realistic and achievable. TGCG's managers, writers and project management staff are highly experienced in driving publication plans forward, liaising effectively with both authors and sponsors to ensure timely delivery of publications. Strategic publishing can also be incorporated into a programme of integrated healthcare communications, ensuring that all communication activities are co-ordinated through a product's lifecycle.
>
> **Marketing and strategic consultancy**
>
> TGCG has extensive in-house expertise in marketing and strategic consultancy. This expertise ranges developing the overall brand vision, positioning and promotional platform, through to detailed development of competitive claims, backed by a sound understanding of the regulatory and reimbursement environment. Such work has previously involved direct input into the design and development of clinical trials and health outcomes and programmes.

72. Amgen hired GCC to ghostwrite a series of articles promoting Aranesp and Neulasta.

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73. At least three papers were published that were ghostwritten by GCC for Amgen. On information and belief, Amgen had close ties to GCC and GCC wrote other articles on these drugs whose identity is not known due to ghostwriting. Each article promoted drugs manufactured by Amgen. Each article contains an overlap of words and phrases that indicate they had common authorship, despite their lack of disclosed relatedness. The articles are as follows:

The Benefits of Haematopoietic Growth Factors in the Management of Gynaecological Oncology ("Dale Article")

Optimising Management of Neutropenia and Anaemia in Cancer Chemotherapy – Advances in Cytokine Therapy ("Siena Article")

Pegfilgrastim: A Recent Advance in the Prophylaxis of Chemotherapy-Induced Neutropenia ("Waladkhani Article")

74. GCC authored each of these articles and allowed the above-mentioned authors to take the credit.

75. An employee of GCC, Andree Cole, has admitted the firm's involvement in all three papers.

76. The chronology of how "Dale's" paper was created and published in the Eur. J. Gynaecol. Oncol. 25:133-144, is as follows, as recounted by a document authored by GCC:

77. Amgen Europe GmbH ("Amgen") was a sponsor of a European School of Oncology (ESO) course that took place in Tuscany, Italy on the 5-9 August 2002. As part of their sponsorship, Amgen was invited as a speaker for the topic New Insights for Managing Neutropenia and Anaemia in Cancer Patients. Amgen invited Dale to make this presentation and travel, accommodation and any honoraria were arranged directly by Amgen and Professor Dale.

78. Professor Dale sent his proposed slides and outline to Amgen on July 5, 2002 and asked for their comments.

79. Amgen approached GCC on July 9, 2002 and asked if they would provide revisions and make recommendations for adaptations to Dale's PowerPoint presentation.

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80. GCC sent a proposed, revised slide set to Professor Dale on July 26. Suggested changes were made to the general flow of the presentation and additional slides included to cover darbepoetin and pegfilgrastim for Professor Dale's consideration only.

81. Professor Dale responded on July 28, 2002, advising that he had not realized that Amgen had requested this work to be carried out on his slides.

82. A revised slide set was forwarded to Professor Dale on July 30.

83. Professor Dale acknowledged receipt of revised slide set and requested that GCC send the final slide set to the ESO organizers.

84. Following Professor Dale's presentation at the ESO course, the editor of the Distinguished Expert Series of the European Journal of Gynaecological Oncology (EJGO), Dr. Péter Bősze, invited Professor Dale to prepare a paper on the uses of haematopoietic growth factors. On September 19, 2002, Professor Dale accepted this invitation and stated that he would try to get the paper to EJGO within 2 months.

85. On September 27, 2002, GCC advised Amgen that Professor Dale would require medical writing assistance and asked whether Amgen would like a quotation for such services. This was agreed to by Amgen.

86. On October 29, 2002 GCC wrote to Professor Dale to re-confirm whether writing assistance would be required and offered to put together a timeline. Professor Dale wrote back asking for GCC's experience in chemotherapy-induced neutropenia and suggested that GCC should use his slide set from the ESO course to develop the paper.

87. A quote for Medical Writing assistance was sent to Amgen on October 30, 2002 and approval/sign-off of the quote was received by GCC from Amgen on October 31, 2002. The quote covered:

- Development of an outline
- Liaison with Professor Dale and Amgen to obtain approval
- Ordering references

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- Development of first draft
- Liaison with Professor Dale and Amgen for comments
- Development of second draft
- Liaison with Professor Dale and Amgen for approval
- Provision of final draft
- Assistance in preparing the submission package

88. Once the GCC writer was satisfied with her first draft (November 28, 2002), it then went through various stages of review internally before being sent to ***Professor Dale and Amgen***. Initially, an editor reviewed the draft manuscript to ensure that the language used was appropriate for the readership of the journal, that correct English grammar was used throughout and to ensure a clear concise flow. Once the editor's comments had been incorporated (December 2, 2002), the manuscript was then reviewed by two Editorial Team Leaders, one each from the Neulasta and Aranesp teams, because both products were discussed in the review. The Editorial Team Leaders reviewed the first draft on December 3, 2002 to check for scientific accuracy, a clear and logical sequence to the flow of the manuscript and that it followed the agreed outline.

89. The first draft was sent to Professor Dale and Amgen on December 4, 2002. ***Amgen also received a copy of all the marked-up references in accordance with GCC's Guidance for External Vendors on Generating Materials with Medical Scientific Content.*** Comments were requested by December 11, 2002. No comments were received by this date, so the deadline was extended until December 18, 2002. Suggested comments were received from Amgen on December 19, 2002, and January 15 & 22, 2003.

90. Amendments received from Amgen were incorporated and revised text sent to Professor Dale and Amgen on January 27, 2003, requesting comments and final approval by February 11,2003. Professor Dale was advised that following his approval, we would prepare a submission pack for him to submit the article directly to EJGO.

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91. On February 11, 2003 Professor Dale writes to GCC advising that "The manuscript is excellent. I approve and please proceed to send to editor and publisher. Thank you."

92. The article was published with no reference to Amgen or GCC.

93. In a subsequent investigation by the University of Washington, the investigator concluded that GCC admitted its involvement in writing the paper. It specifically found that "there is evidence of Dr. Dale used medical writing assistance."

94. On November 5, 2006, EJGO published an errata stating as follows:

> ***Erratum:*** A paper by D.C. Dale published in the EJGO 2004, 25, 133-144 entitled "The benefits of haematopoietic growth factors in the management of gynaecological oncology" inadvertently omitted an acknowledgement of editorial assistance of Jackie Williams from Gardiner-Caldwell Communications and whose services were paid for by Amgen Europe.

95. Amgen was aware of Dale's publication and on information and belief used this article in promoting Aranesp and Neulasta.

96. The Siena and Waldadkhani articles were prepared in a similar fashion. Each was ghostwritten by Amgen and GCC, each was then published with no attribution or disclosure of the role of Amgen or GCC.

G. The Articles Promoted Off-Label Use

97. These articles promoted off-label use of Aranesp. The label for Aranesp was a specific dose indicated as approved by the FDA.

98. The recommended starting dose for Aranesp administered weekly is 2.25 mcg/kg as a SC injection.

99. The recommended starting dose for Aranesp administered once every 3 weeks (Q3W) is 500 mcg as a SC injection.

100. For both dosing schedules, the dose should be adjusted for each patient to maintain a target hemoglobin not to exceed 12 g/dL. If the hemoglobin exceeds 13 g/dL, doses

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should be temporarily withheld until the hemoglobin falls to 12 g/dL. At this point, therapy should be reinitiated at a dose 40% below the previous dose. If the rate of hemoglobin increase is more than 1.0 g/dL per 2-week period or when the hemoglobin exceeds 11 g/dL, the dose should be reduced by 40% of the previous dose.

101. For patients receiving weekly administration, if there is less than a 1.0 g/dL increase in hemoglobin after 6 weeks of therapy, the dose of Aranesp should be increased up to 4.5 mcg/kg.

102. Siena, citing the same statistics and using the same phrases as Dale, due to a common ghost author, suggested that "front loading" of Aranesp was beneficial. Using the same phrases as Dale, he wrote that front loading "may increase the speed of response."

103. Thus, the Siena article advocated "front loading" use of Aranesp. It advocated an initial dose of 4.5 mcg/kg per week followed by doses of 1.5 or 2.25 mcg/kg per week. The FDA approved dose is 2.25 mcg/kg per week.

104. The Dale article advocated front loading as well, noting that such a program "may increase the speed of response and increase the proportion of patients responding" versus standard EPO therapy. Dale advocated an initial dose of 4.5 mcg/kg per week, again a dose that is higher than the approved label. Dale notes that this "optimal dose and schedule of darbepoetin alfa were explored in a recent clinical trial...."

105. Aranesp's label requires that if the approved dosing (based on simple pharmacokinetic dosing principles intended to achieve a gradual rise to steady state levels) results in a hemoglobin (Hgb) level approaching 12 g/dL that the dose should be reduced by 25%. In contrast, in reviewing a phase 3 trial of Aranesp, Dale emphasizes the definition of a hematopoietic response as including "a Hgb level of $\geq$ 12 g/dL" and, with respect to the more rapid front loading dosing, advocates maintaining Hgb levels exceeding 12 g/dL by continuation of Aranesp with a maintenance dose.

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106. In addition, Dale wrote that pegfilgrastim (Neulasta) was superior to filgrastim (Neupogen):

> Overall, only 11% of patients receiving pegfilgrastim developed FN compared with 19% of patients receiving filgrastim, suggesting that pegfilgrastim may have superior efficacy of the management of neutropenic conditions compared with filgrastim.[2]

107. The FDA approved label only found that Neulasta was comparable to Neupogen. It did not find that Neulasta had "superior efficacy" over Neupogen. Further, the label notes that the real measure of efficacy is the duration of neutropenia, not the reduction of febrile neutropenia. The "Dale" paper promotes Neulasta based on a measure of efficacy not supported by the label.

108. The Waladkhani article also promotes the efficacy of Neulasta beyond the FDA approved label. Citing the same statistics cited to by Dale, a result of the common ghost author, Waladkhani states that patients have a "significantly lower risk" of febrile neutropenia if they use Neulasta. He then goes on to pitch Neulasta as having several potential benefits compared to Neupogen, including convenience to nurses and patents. Such benefits are not contained in the FDA approved label.

109. Siena also promoted Neulasta as more efficient than Neupogen. Citing the same statistics as Dale and Waladkhani, he claimed that Neulasta appeared to lower febrile neutropenia and made patients' lives easier.

110. There are safety concerns related to the use of erythropoietin and Aranesp (which, along with other derivatives of erythropoietin are collectively known as erythropoiesis-stimulating agents (ESAs)). One source of concern involves cardiovascular effects of higher target hemoglobin values. On November 16, 2006, the US Food and Drug Administration (FDA) issued an alert (http://www.fda.gov/cder/drug/infopage/RHE/default.htm) to healthcare professionals regarding the significantly increased risk for serious and life-threatening

[2] FN is febrile neutropenia.

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cardiovascular complications associated with normalization of hemoglobin levels in patients receiving ESAs. The warning was based primarily on data from the Correction of Hemoglobin and Outcomes in Renal Insufficiency (CHOIR) study that was published the same day in the New England Journal of Medicine. The CHOIR study found that the rate of cardiovascular events was significantly increased in the group of patients with higher target hemoglobin values, as evaluated using a composite vascular end point consisting of all-cause mortality, congestive heart failure, myocardial infarction, and stroke. The FDA noted that a prior study had arrived at a similar conclusion. Although the CHOIR study addressed use of ESAs in the treatment of chronic renal failure, the FDA warning was also directed at treatment of cancer patients and concluded that "study findings underscore the importance of following the currently approved prescribing information for Procrit, Epogen, and Aranesp, including the dosing recommendation that the target hemoglobin not exceed 12 g/dL." Other safety concerns relate to the possibility that use of Aranesp in cancer patients may promote tumor growth, prompting a review of Aranesp safety by the FDA Oncologic Drugs Advisory Committee on May 4, 2004, which in turn led to a revision of label safety warnings on December 16, 2004.

111. In Dale's paper, in the background to anemia section, he notes that anemia is a complication of both cancer itself and of chemotherapy. A reader would then be led to believe that the recommendations for Aranesp apply to all anemic cancer patients, not just those where the anemia is due to the effect of concomitantly administered chemotherapy (the only indication on the label). He specifically mentions Aranesp as an alternative to transfusion. Clinical studies now indicate that Aranesp is not an effective treatment and is dangerous when used to treat cancer anemia not related to chemotherapy. It was in precisely that setting that greater deaths were observed, prompting Sean Harper, M.D., Senior Vice President Global Development and Corporate Chief Medical Officer of Amgen to issue a letter to health care professionals on January 26, 2007 (http://www.fda.gov/medwatch/safety/2007/Aranesp_DHCP_012707.htm):

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> Amgen wishes to inform you of the results of a large, multicenter, randomized, placebo-controlled study showing that Aranesp was ineffective in reducing RBC transfusions in patients with cancer who have anemia that is not due to concurrent chemotherapy. In addition, this study showed higher mortality in patients receiving Aranesp. In the study, Aranesp® (darbepoetin alfa) was compared to placebo in patients with active malignant disease not receiving or expected to receive chemotherapy or radiation therapy. This study was designed to establish the effectiveness of Aranesp in this new indication and failed to meet its primary endpoint of reducing RBC transfusions in the Aranesp treatment group. This study was not optimal in design to establish the effect on survival, a safety endpoint, however more deaths occurred in the Aranesp treatment group when compared to the placebo group.

112. The same thing is true of Siena who states: "This review focuses on the use of darbapoietin alpha to . . . optimize the treatment of anemia in patients with cancer." (NOT anemia in cancer chemotherapy-related anemia.) Thus, both articles were promoting off label use for all cancer patients.

H. Amgen's Ghostwriting of Other Articles

113. The foregoing allegations indicate that Amgen had a relationship with GCC whereby GCC would ghostwrite articles for Amgen. It is likely that the three articles, discovered through the investigative work of the relator, are not the only ghostwritten articles concerning Aranesp and Neulasta that promote off label uses. This would also be true in the area of Aranesp and its use for renal disease.

114. The combination of the cited ghostwritten articles and the unknown ghostwritten articles, contributed to the use of these drugs off-label. Each time such a use took place in a setting where government reimbursement occurs resulted in a false claim.

I. The Federal Government Spent Billions on the Amgen Drugs

115. U.S. sales for Aranesp were as follows:

2003: $980 million
2004: $1.53 billion
2005: $2.10 billion
First 9 months of 2006: $2.03 billion

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116. Neulasta U.S. sales were as follows:

2003: $1.17 billion
2004: $1.47 billion
2005: $1.90 billion
First 9 months of 2006: $1.63 billion

117. A substantial amount of the sales of Aranesp and Neulasta were paid by governmental agencies.

COUNT I

FALSE CLAIMS ACT
31 U.S.C. §§ 3729(A)(1) and (A)(2)

118. Plaintiff realleges and incorporates by reference the preceding allegations.

119. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

120. By virtue of the acts described above, defendants knowingly presented or caused to be presented false or fraudulent claims to the United States Government for payment or approval.

121. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Government to approve and pay such false and fraudulent claims.

122. Each prescription that was written as a result of defendants' illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

123. Plaintiff cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

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124. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by the defendants, paid and continues to pay the claims that would not be paid but for defendants' false and illegal off-label marketing practices and illegal kickbacks.

125. By reason of the defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial. Federal health insurance programs have paid millions of claims, amounting many hundreds of millions of dollars for off-label prescriptions for indications that were not approved by the FDA.

COUNT II

CALIFORNIA FALSE CLAIMS ACT
Cal. Govt. Code § 12651(A)(1) and 2

126. Plaintiff realleges and incorporates by reference the preceding allegations.

127. This is a claim for treble damages and penalties under the California False Claims Act.

128. By virtue of the acts described above, defendants knowingly presented or caused to be presented false or fraudulent claims to the California State Government for payment or approval.

129. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

130. Each prescription that was written as a result of defendants' illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

131. Plaintiff cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false claims were presented by thousands of separate

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entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

132. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for the false and illegal off-label marketing practices and illegal kickbacks.

133. By reason of the defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

134. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT III

DELAWARE FALSE CLAIMS AND REPORTING ACT
6 Del. C. § 1201(A)(1) and (2)

135. Plaintiff realleges and incorporates by reference the preceding allegations.

136. This is a claim for treble damages and penalties under the Delaware False Claims and Reporting Act.

137. By virtue of the acts described above, defendants knowingly presented or caused to be presented false or fraudulent claims to the Delaware State Government for payment or approval.

138. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

139. Each prescription that was written as a result of defendants' illegal marketing practices and illegal kickbacks represents a false or fraudulent record or statement. And, each

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claim for reimbursement for such off-label prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

140. Plaintiff cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

141. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' false and illegal off-label marketing practices and illegal kickbacks.

142. By reason of the defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

143. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT V

FLORIDA FALSE CLAIMS ACT
Fla. Stat. Ann. § 68.082(2)

144. Plaintiff realleges and incorporates by reference the preceding allegations.

145. This is a claim for treble damages and penalties under the Florida False Claims Act.

146. By virtue of the acts described above, defendants knowingly presented or caused to be presented false or fraudulent claims to the Florida State Government for payment or approval.

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147. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

148. Each prescription that was written as a result of defendants' illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

149. Plaintiff cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

150. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' false and illegal off-label marketing practices and illegal kickbacks.

151. By reason of the defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

152. The State of Florida is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT V

HAWAII FALSE CLAIMS ACT
Haw. Rev. Stat. § 661-21(A)

153. Plaintiff realleges and incorporates by reference the preceding allegations.

154. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

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155. By virtue of the acts described above, defendants knowingly presented or caused to be presented false or fraudulent claims to the Hawaii State Government for payment or approval.

156. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

157. Each prescription that was written as a result of defendants' illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

158. Plaintiff cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

159. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for Amgen's false and illegal off-label marketing practices and illegal kickbacks.

160. By reason of the defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

161. The State of Hawaii is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

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COUNT VI

ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT
740 Ill. Compo Stat. § 175/3(A)(L), (2)

162. Plaintiff realleges and incorporates by reference the preceding allegations.

163. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward and Protection Act.

164. By virtue of the acts described above, defendants knowingly presented or caused to be presented false or fraudulent claims to the Illinois State Government for payment or approval.

165. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

166. Each prescription that was written as a result of defendants' illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

167. Plaintiff cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

168. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants false and illegal off-label marketing practices and illegal kickbacks.

169. By reason of the defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

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170. The State of Illinois is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT VII

MASSACHUSETTS FALSE CLAIMS LAW
Mass. Gen. Laws ch. 12 § 5B(L), (2)

171. Plaintiff realleges and incorporates by reference the preceding allegations.

172. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

173. By virtue of the acts described above, defendants knowingly presented or caused to be presented false or fraudulent claims to the Massachusetts State Government for payment or approval.

174. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

175. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

176. Plaintiff cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

177. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

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defendants, paid and continues to pay the claims that would not be paid but for defendants' false and illegal off-label marketing practices and illegal kickbacks.

178. By reason of the defendants' acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

179. The State of Massachusetts is entitled to the maximum penalty of$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT VIII

NEVADA FALSE CLAIMS ACT
Nev. Rev. Stat. Ann. § 357.040(1)(A), (B)

180. Plaintiff realleges and incorporates by reference the preceding allegations.

181. This is a claim for treble damages and penalties under the Nevada False Claims Act.

182. By virtue of the acts described above, defendants knowingly presented or caused to be presented false or fraudulent claims to the Nevada State Government for payment or approval.

183. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

184. Each prescription that was written as a result of defendants' illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

185. Plaintiff cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false claims were presented by thousands of separate

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entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

186. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' false and illegal off-label marketing practices and illegal kickbacks.

187. By reason of the defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

188. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT IX

TENNESSEE MEDICAID FALSE CLAIMS ACT
Tenn. Code Ann. § 71-5-182(A)(1)

189. Plaintiff realleges and incorporates by reference the preceding allegations.

190. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Law.

191. By virtue of the acts described above, defendants knowingly presented or caused to be presented false or fraudulent claims to the Tennessee State Government for payment or approval.

192. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

193. Each prescription that was written as a result of defendants' illegal marketing practices represents a false or fraudulent record or statement. And, each claim for

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reimbursement for such off-label prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

194. Plaintiff cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

195. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' false and illegal off-label marketing practices and illegal kickbacks.

196. By reason of the defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

197. The State of Tennessee is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT X

TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code Ann. § 36.002

198. Plaintiff realleges and incorporates by reference the preceding allegations.

199. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

200. By virtue of the acts described above, defendants knowingly presented or caused to be presented false or fraudulent claims to the Texas State Government for payment or approval.

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201. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

202. Each prescription that was written as a result of defendants' illegal marketing practices and illegal kickbacks represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

203. Plaintiff cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

204. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' false and illegal off-label marketing practices and illegal kickbacks.

205. By reason of the defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

206. The State of Texas is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT XI

VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01 -216.3(A)(L), (2)

207. Plaintiff realleges and incorporates by reference the preceding allegations.

208. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

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209. By virtue of the acts described above, defendants knowingly presented or caused to be presented false or fraudulent claims to the Virginia State Government for payment or approval.

210. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

211. Each prescription that was written as a result of defendants' illegal marketing practices and illegal kickbacks represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

212. Plaintiff cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

213. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' false and illegal off-label marketing practices and illegal kickbacks.

214. By reason of the defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

215. The State of Virginia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

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COUNT XII

DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code Ann. § 1-1188.L4(A)(1), (2)

216. Plaintiff realleges and incorporates by reference the preceding allegations.

217. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.

218. By virtue of the acts described above, defendants knowingly presented or caused to be presented false or fraudulent claims to the District of Columbia Government for payment or approval.

219. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

220. Each prescription that was written as a result of defendants' illegal marketing practices and illegal kickbacks represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

221. Plaintiff cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

222. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' false and illegal off-label marketing practices and illegal kickbacks.

223. By reason of the defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

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224. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

V. PRAYER

a. that defendants cease and desist from violating 31 U.S.C. § 3729 *et seq.* and the equivalent provisions of the States and the District of Columbia's statutes set forth above;

b. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729;

c. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of California has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code § 12651(a);

d. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. § 1201(a);

e. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Fla. Stat. Ann. § 68.082(2);

f. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. § 661-21(a);

g. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of 740 Ill. Compo Stat. § 175/3(a);

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h. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. ch. 12 § 5B;

i. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. § 357.040(1)(a), (b);

j. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. § 71-5-182(a)(1);

k. that this Court enter judgment against defendants an amount equal to three times the amount of damages the State of Texas has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. § 36.002;

l. that this Court enter judgment against defendants in amount equal to three times the amount of damages the State of Virginia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. § 8.01-216.3(a)(1), (2);

m. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 1-1188.14(a)(1), (2);

n. that plaintiff be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act and the equivalent provisions of the States and the District of Columbia statutes set forth above;

o. that plaintiff be awarded all costs of this action, including attorneys' fees, costs, and expenses pursuant to 31 U.S.C. § 3730(d) and the equivalent provisions of the States and the District of Columbia statutes set forth above; and

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p. that the United States and plaintiff/relator be granted all such other relief as the Court deems just and proper.

DATED: February 15, 2007

HAGENS BERMAN SOBOL SHAPIRO LLP

By _____
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